



FEDERAL TRADE COMMISSION

[File No. 211 0101 / Docket No. C-4754]

ANI/Novitium; Analysis of Agreement Containing Consent Orders to Aid Public

Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of Federal law prohibiting unfair methods of competition. The attached Analysis of Proposed Consent Orders to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY**

INFORMATION section below. Please write: “ANI/Novitium; File No. 211 0101” on your comment, and file your comment online at <https://www.regulations.gov> by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kari Wallace (202-326-3085), Bureau of Competition, Federal Trade Commission, 400 7th Street SW, Washington, DC

20024.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis of Agreement Containing Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Website at this web address: <https://www.ftc.gov/news-events/commission-actions>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Write “ANI/Novitium; File No. 211 0101” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the <https://www.regulations.gov> website.

Due to protective actions in response to the COVID-19 pandemic and the agency’s heightened security screening, postal mail addressed to the Commission will be delayed. We strongly encourage you to submit your comments online through the <https://www.regulations.gov> website.

If you prefer to file your comment on paper, write “ANI/Novitium; File No. 211 0101” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution

Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at <https://www.regulations.gov>, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on <https://www.regulations.gov> – as legally required by FTC Rule 4.9(b) – we cannot redact or remove your comment from that website, unless you

submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at <https://www.ftc.gov> to read this Notice and the news release describing this matter. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it receives on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from ANI Pharmaceuticals, Inc. ("ANI") and Novitium Pharma LLC and Esjay LLC (collectively, "Novitium") designed to remedy the anticompetitive effects resulting from ANI's acquisition of the non-corporate interests of Novitium. Pursuant to an agreement dated March 8, 2021, ANI proposes to acquire Novitium in a transaction valued at approximately \$210 million. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening future competition in the following two U.S. markets: (1) generic SMX-TMP oral suspension; and (2) generic dexamethasone tablets. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

Under the terms of the proposed Decision and Order ("Order"), Respondents are required to divest all of ANI's rights and assets related to the following two products to

Prasco LLC (“Prasco”): (1) generic sulfamethoxazole-trimethoprim (“SMX-TMP”) oral suspension; and (2) generic dexamethasone tablets. The Commission and Respondents have agreed to an Order to Maintain Assets that requires Respondents to operate and maintain each divestiture product in the normal course of business until the products are ultimately divested to Prasco. The Commission also issued the Order to Maintain Assets.

The Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the Consent Agreement, modify it, or make final the proposed Order.

I. The Respondents

Respondent ANI is a public specialty pharmaceutical company headquartered in Baudette, Minnesota selling both branded and generic pharmaceutical products.

Respondent Novitium is a privately-held company based in East Windsor, New Jersey. The company develops, manufactures, and commercializes generic pharmaceutical products.

II. The Products and Structure of the Markets

In human pharmaceutical markets, price(s) generally decreases as the number of generic competitors increase. Prices continue to decrease incrementally with the entry of the second, third, fourth, and further pharmaceutical competitors. Accordingly, a reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Acquisition would reduce future competition in the SMX-TMP oral suspension market, where ANI is a current competitor and Novitium is likely to enter the market. Generic SMX-TMP oral suspension is an antibiotic product used to treat a

variety of infections. Five companies, including ANI, currently market the product in the United States, but at least one has had difficulty manufacturing the product. Novitium is one of a limited number of suppliers capable of entering the market for SMX-TMP oral suspension in the near future.

Similarly, the Proposed Acquisition would reduce future competition in the 4 mg strength of generic dexamethasone tablets market, where both ANI and Novitium are likely to enter the market in the near future. Generic dexamethasone tablets are an oral steroid product used to treat inflammation associated with a variety of conditions. Dexamethasone tablets are available in a variety of strengths, although the most widely used strength is the 4 mg strength. Only two companies sell the 4 mg strength of dexamethasone tablets in the United States today, and ANI and Novitium are two of a limited number of companies likely to enter the market in the near future.

III. Entry

Entry into the two markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

IV. Competitive Effects

The Proposed Acquisition likely would delay or reduce the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in the two markets at issue. While five companies, including ANI, currently market the generic SMX-TMP product in the United States, at least one has had difficulty manufacturing the product, and Novitium is one of a limited number of suppliers capable of entering the market in the near future. In the generic dexamethasone tablets market, only two companies sell the 4 mg strength in the United States today and ANI and Novitium are two of a limited number of companies entering the market in the near

future. Absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay higher prices for the aforementioned generic products.

V. The Proposed Order and the Order To Maintain Assets

The proposed Order and the Order to Maintain Assets effectively remedy the competitive concerns raised by the Proposed Combination for the two generic pharmaceutical product areas at issue. Pursuant to the proposed Order, the parties are required to divest ANI's rights and assets related to the two products to Prasco. The parties must accomplish these divestitures no later than ten days after the Proposed Combination is consummated. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

While ANI and Novitium do not compete against each other in the market for generic erythromycin and ethylsuccinate granules for oral suspension, Novitium has an unexecuted option to acquire a product from another company and ANI sells a product today. The proposed Order requires prior Commission approval before ANI or Novitium may acquire any rights or interests in certain products containing, as the active pharmaceutical ingredients, erythromycin and ethylsuccinate. This provision allows the Commission to evaluate whether a future acquisition of the erythromycin and ethylsuccinate product would reduce competition at the time the acquisition is proposed. The proposed Order also requires ANI and Novitium to seek Commission approval before acquiring any other SMX-TMP or dexamethasone tablet product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Combination. Prasco is a capable purchaser with management and employees who have experience marketing and distributing generic pharmaceutical products. It will be able to replicate the competition otherwise lost from the Proposed Combination.

The proposed Order contains several provisions to help ensure the divestitures are

successful. ANI will supply Prasco with SMX-TMP oral suspension and dexamethasone tablets for up to three years while the company transfers the manufacturing technology to Prasco's contract manufacturing designee. The proposed Order also requires ANI to provide transitional services to Prasco to assist it in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to have the products manufactured in substantially the same manner and quality employed or achieved by ANI. It also includes advice and training from knowledgeable employees of the parties. Further, the proposed Order requires prior Commission approval before Prasco may sell, license, or otherwise convey any of the assets divested pursuant to the proposed Order.

Under the proposed Order, the Commission also will appoint a Monitor to ensure ANI and Novitium comply with their obligations under the proposed Order and Order to Maintain Assets. The Commission has appointed Denise Smart of Smart Consulting Group, LLC as the Monitor. Ms. Smart is an expert in areas such as pharmaceutical R&D, regulatory approval, manufacturing and supply, and marketing, and she has over thirty years of experience in the pharmaceutical area and has provided consulting services in healthcare business development to major pharmaceutical companies, biotechnology companies, universities, and other government agencies, including the FDA, Department of Defense, and Health and Human Services.

The proposed Order also contains a prior approval provision relating to Prasco, which prohibits Prasco from selling the acquired products for a combined period of ten years after the Order is issued, except to an acquirer that receives the prior approval of the Commission.

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the

proposed Order and does not modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2021-26294 Filed: 12/2/2021 8:45 am; Publication Date: 12/3/2021]